

## **REMARKS**

Claim 1 has been rejected under 35 USC 102(b) as anticipated by Krueger et al. Patent Number 5,868,253; claim 22 has been rejected under 35 USC 102(b) as anticipated by Bowman et al. Patent Number 4,736,850 and claims 1 and 19 have been rejected under 35 USC 103(a) in view of Bowman et al. '850 when combined with Krueger et al. '253.

The term "linear" is given its ordinary and normal usage in line 9, namely resembling a line or straight. It refers to the straight depression or trough formed in the insert to hold an implant 100 as shown in Figures 1, 2, 8 and 9 inside the cavity of the inner container in a predetermined position so that the tissue implant is held in place against the walls of the inner container. Conversely Figure 15 shows a stepped trough which is not linear. There is clear disclosure for defining the trough of the insert in this manner. Neither of the applied references show such a trough to hold an implant placed therein against the inner container base. As previously noted Bowman et al. '850 patent is directed to a cell harvesting kit comprising three trays contained in a packaging container 11. The first tray is an outer tray 12 with a lid 13. The lid 13 is sealed to a flange formed by the tray 12 and abuts against the inner surface of the side walls of the packaging container 11. A second component tray 14 is sized to fit in the cavity formed by the outer tray and is provided with a lid. A third process tray 31 is seated on the base of the component tray and is secured to the base. The process tray 31 defines a trough 30 located within the center of the process tray. The process tray is empty when the container is sealed and is only used during surgery. This trough 30 holds the vein which is removed from the patient and **cannula are placed in each end of the vein. The cannula holding the vein are then placed in slots 32 located at each end of the trough 30. The cannula are held in the slots as the vein must be rinsed, cut and filled with Diapase.** Bowman et al. '850

is not meant to hold an allograft tissue form in storage as it would fall out of the trough 30 during movement of the container and be almost impossible to place back in the trough once it was dislodged. The trough 30 simply acts as a seat for treatment of a vein taken from the patient being operated upon. This is an autologous procedure meaning that the vein is taken from the patient being operated upon and is not an allograft implant requiring storage of the same prior to use in another patient. If the Bowman et al. '850 trough 30 is applied against claim 1 with the linear trough, then it cannot be applied against Claim 22 with the stepped trough or vice versa. It cannot be argued to have both configurations simultaneously. None of the references show the trough positioned with respect to the base wall of the container to limit implant movement. Neither Bowman or Krueger et al show an angled end wall of Claim 19 which forms a seat for the insert container housing which allows the same to take up less space than a container placed on its base, an important aspect as freezer space is limited during freeze drying. Thus there can be no combining of the two references. The insert member is a single piece allowing easy insertion of the same in the container unlike that of Krueger et al. '253. The process tray of Bowman et al. "736 would have an implant placed in trough 30 fall out during storage and be deposited in the large cavity causing lipid seepage from the implant through the entire container. Furthermore the process tray is either fixed to container 14 or it floats within the cavity. The process tray is not constructed to hold an implant which is being stored.

The Krueger et al. '253 patent discloses a mechanical heart valve package with an outer container, an inner heart valve container seated in the outer container and a two piece complex hinged retainer member mounted in the inner container to keep the heart valve in place. There is no trough for implant retention shown in Krueger. The hinged container member is mounted into the

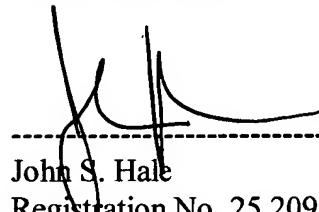
inner heart valve container through the use of a complex structure on the inner container. The '253 patent requires complex orientation of the component parts to arrive at a locking position for the implant.

None of the references teach a single piece removable insert for holding the implant in a predetermined position for storage of the implant, a stepped or linear trough holding the implant during storage or an angled container wall allowing the same to be placed on end for reducing space during freezing.

Applicant again submits that the cited references do not teach, anticipate, or obviate the present invention either singularly or in combination and requests that the application be favorably reexamined and passed to issue. If any additional charges are required, please charge Deposit Account Number 07-1340.

Respectfully submitted,

GIPPLE & HALE



John S. Hale  
Registration No. 25,209

6665-A Old Dominion Drive  
McLean, Virginia 22101  
(703) 448-1770 ext. 304  
Attorney Reference: X-9353

Not an amendment.  
Do not enter as an amendment.

## ATTACHMENT

Claim 1. A container assembly for storing sterile allograft tissue implant forms in a sterile condition comprising:

an outer container defining an open faced cavity and a flange extending outward from said cavity, a stepped recess formed in said flange surrounding said cavity;

an inner container defining a base, walls integrally formed with said base, said walls defining an open faced cavity and a flange extending outward from said cavity, said inner container flange being of a dimension to fit into said stepped recess of said outer container,

[[an]] a one piece insert member sized to fit into said inner container cavity and removable from said inner container cavity, said insert member defining a linear shaped structure therein to hold a tissue implant form adjacent said inner container base;

a permeable cover sealed to the flange of the inner container covering said inner container cavity; and

an outer cover sealed to the flange of the outer container covering said outer container cavity.

Claim 19. A container for storing sterile allograft bone tissue forms comprising: a blister container housing defining an open faced cavity and a flange extending around said cavity outward from said cavity, said housing comprising a first end wall, side walls connected to said first end wall and an angularly oriented planar second end wall section angled toward said first end wall which forms a seat for said blister container housing, all of said walls being integrally connected with a base to form an interior cavity adapted to hold an insert member,

an insert member sized to fit into said container cavity, said insert member comprising a one piece housing defining a linear channel formed therein to hold a tissue implant form and having, said insert member being provided with a tab member extending from one of it's walls; and a permeable cover sealed to the flange of the inner said blister container covering said container cavity.

Claim 22. (Currently Amended) A container for storing sterile tissue forms comprising: a blister container housing defining an open faced cavity and a flange extending outward from said cavity, said housing comprising a front end wall, side walls connected to said front end wall and a rear end wall, all of said walls being integrally connected with a base to form an interior cavity adapted to hold [[an]] a removable insert member,

    said insert member being sized to fit into said container cavity, said insert member comprising a housing defining a stepped arcuate groove to hold a tissue implant form in a predetermined position adjacent said container housing base and having being provided with a tab member extending from a housing wall; and

    a removable cover sealed to the flange of the inner container covering said container cavity.